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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/937,678 | 09/28/2001 | Eric Goutay | PF 100 PCT US | 5103 |

25666 7590 01/23/2004

THE FIRM OF HUESCHEN AND SAGE
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350 EAST MICHIGAN AVENUE
KALAMAZOO, MI 49007

EXAMINER

EVANS, CHARESSE L

| | |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

1615

DATE MAILED: 01/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/937,678

Applicant(s)

GOUTAY ET AL.

Examiner

Charesse L. Evans

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26-36 and 39-42 is/are rejected.
- 7) ☒ Claim(s) 37,38,43 and 44 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Please note the new contact number for examiner and supervisor at end of
action, effective after February 3, 2004.

Action Summary

This application is a 371 of PCT/FR00/00803, filed March 3, 2000.

Acknowledgement is made of applicant's amendment and response, and IDS, filed October 23, 2003.

Claims 45-50 were previously withdrawn and claims 26-44 are currently active in this action.

Response to Arguments

Applicant's arguments filed October 23, 2003, have been fully considered but they are not persuasive.

Applicant attempts to distinguish the claimed invention from the prior art by claiming that the instant composition has a disintegration time of less than one minute, whereas the cited prior art teaches a dissolution time which varies from 2-4

minutes. The cited prior art reference does teach a disintegration range of 2 to 4 minutes, however, it is the position of the examiner that the claimed disintegration time is a limitation that would be routinely determined by one of ordinary skill in the art, through minimal experimentation, as being suitable, absent the presentation of some unusual and/or unexpected result. The results must be those that accrue from the specific limitations. Absent a clear showing of criticality, the determination of the particular range is within the skill of the ordinary worker as part of the process of normal optimization.

Additionally, regarding applicant's assertion that the cited prior art lacks a teaching of an 'expanded structure' because the reference compositions, which may be characterized by a porous structure formed on lyophilization, rather than the exhibition of an 'expanded structure' formed on evaporation, examiner disagrees. Applicant is attempting to argue the method by which the expanded structure is formed, in claims directed to a composition. In a composition, patentable weight is not given to the reason for including a component or to the method by which the composition is formed, as long as all of the necessary components are present. Furthermore, when a component is included in a composition, all of its properties and advantages are inherent to the composition.

Finally, even if the lyophilization versus evaporation argument were valid, applicant's position would fail here as well. The independent claim is directed to an

'... expanded structure....' and does not contain the limitation requiring that the expanded structure be formed on evaporation.

Applicant argues that the cited prior art reference is not relevant to the patentability of the instant composition because it does not disclose compositions having an imperceptible texture upon contact with the buccal mucosal membranes. Examiner disagrees with applicant's position. Applicant is attempting to argue a limitation that is not present within the claim language. Applicant is advised to include this limitation within the claims for consideration by the examiner.

This rejection is maintained.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory

period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

The last office action, mailed on May 7, 2003, is reproduced below for reference:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order

for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 26-36 and 39-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Derrieu et al (US 5,527,783). The claims are directed to a composition that has a fast-dissolving isotropic microporous expanded structure. [E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted). Derrieu teaches a solid composition based on plants, comprised of an active principle, diluents, binders, coloring and flavors (column 4, lines 7-12). The diluents of preference include lactose and mannitol (column 4, lines 27-28). The binders include gums such as gum Arabic, alginates, pectins, gelatin, xanthan gum, dextrin and polyvinylpyrrolidone (column 4, lines 29-39). The additives used in the referenced invention are those normally used in the pharmaceutical and food industry and are compatible with the active principles present (column 4, lines 39-43).

While the reference does not expressly teach applicant’s claimed percent weights, differences in concentration will not support the patentability of subject

matter encompassed by the prior art unless there is evidence indicating such concentration is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955).

Regarding the disintegration time of less than 1 minute, in a composition claim, patentable weight is not given to the physical parameter or reason for including that component, as long as all of the necessary components are present. Furthermore, when a component is included in a composition, all of its properties and advantages are inherent to the composition. The presence of the component is all that is needed to render obvious applicant's claim.

One of ordinary skill in the art would be motivated to modify the teachings of Derrieu to include a broader spectrum of active agents within the composition with the expectation of being able to utilize the composition across multiple disciplines.

Claim Objections

Claims 37, 38, 43 and 44 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Contact Information


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charesse L. Evans whose telephone number is 703-308-6400 (or at 571-272-0593 after February 3, 2004). The examiner can normally be reached on Monday - Thursday 7:00a - 4:30p; Alternating Fridays 7:00a - 3:30p.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 703-308-2927 (or at 571-272-0602). The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Charesse L. Evans
Examiner
Art Unit 1615

January 14, 2004


THURMAN K. PAGE
SUPERVISORY/PATENT EXAMINER
TECHNOLOGY CENTER 1600